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EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,468	Applicant(s) ALTMAN, SANFORD D.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,11-16,24-28 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,11-16,24-28 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 February 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,099,58 to Sorenson et al.

In the specification and figures, Sorenson discloses the apparatus as claimed by applicant. With regard to claim 1, Sorenson discloses a dual-lumen catheter with an interior or arterial lumen 32 having an inner and outer surface and a distal end, and a proximal end mounted in a hollow hub 12. Sorenson further discloses an exterior or venous lumen 34 with an inner and outer surface, distal end, proximal end, with a single aperture at the distal end (see column 2, lines 40-65, FIG 2). The catheters 32, 34 are

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arranged in a coaxial configuration with the inner or arterial catheter 32 extending beyond the distal end of the outer or venous lumen 34 (see column 2, lines 66-68, FIG 2). The proximal ends of both lumens are attached to a hollow hub 12. While Sorenson does not specifically disclose that the hub is removable, it is the position of the Examiner that a portion of a device is *removable*, that is, capable of being removed from another portion of the device. Sorenson does not disclose that the lumens are permanently attached or bonded to the hub, and once the hub is detached, the inner and outer lumens are capable of movement with regard to one another, permitting the inner lumen to be removed from the outer lumen, thereby meeting the limitations of the claims.

With regard to claims 6-7, as interpreted by the Examiner, Sorenson illustrates that the distal ends of the venous or outer and arterial or inner catheters are tapered (see FIGS 2-3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-5, 11-16, 24, 25, 27, 28, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,099,58 to Sorenson et al in view of US 6,758,836 to Zawacki.

In the specification and figures, Sorenson discloses the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 3-5, as interpreted by the Examiner, Sorenson fails to disclose how far the inner or arterial lumen extends beyond the distal end of the outer, or venous lumen. Zawacki discloses a dual-lumen catheter wherein the inner lumen 30 of catheter 10 is slideable, or adjustable with respect to the distal end of the outer lumen 20 (see column 4, lines 1-18, FIGS 2, 3). Zawacki teaches that the ability to alter the position of the distal end of the inner tube with respect to the outer tube is especially useful in order to relieve blockages in flow. Zawacki's disclosure suggests that the catheter 10 and its lumens 20, 30, are capable of being deployed at the distances claimed by applicant in order to provide for efficient fluid movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the catheter disclosed by Zawacki with the distal ends of the lumens separated by the distance claimed by applicant, in order to provide flexibility in blockage alleviation, as taught by Zawacki.

With regard to claim 11, Sorenson fails to disclose the particular shapes of the catheters. Zawacki discloses that the catheter lumens may comprise a circle-C configuration that are interchangeable with the coaxial configuration (see column 4, lines 45-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to form the catheter disclosed by Sorenson in a circle-C configuration, since Zawacki discloses that such shapes are functional equivalents to the coaxial configuration.

With regard to claims 12-14, Sorenson fails to disclose how far the inner or arterial lumen extends beyond the distal end of the outer, or venous lumen. Zawacki discloses a dual-lumen catheter wherein the inner lumen 30 of catheter 10 is slideable, or adjustable with respect to the distal end of the outer lumen 20 (see column 4, lines 1-18, FIGS 2, 3). Zawacki teaches that the ability to alter the position of the distal end of the inner tube with respect to the outer tube is especially useful in order to relieve blockages in flow. Zawacki's disclosure suggests that the catheter 10 and its lumens 20, 30, are capable of being deployed at the distances claimed by applicant in order to provide for efficient fluid movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the catheter disclosed by Zawacki with the distal ends of the lumens separated by the distance claimed by applicant, in order to provide flexibility in blockage alleviation, as taught by Zawacki.

With regard to claims 15-16, Sorenson illustrates that the distal ends of the venous or outer and arterial or inner catheters are tapered (see FIGS 2-3).

With regard to claims 24 and 25, Sorenson fails to disclose that the distal end of the venous lumen comprises a plurality of shaped apertures. Zawacki illustrates that both the inner and outer lumens, 30, 20/24, comprise a plurality of circular apertures 36, 26 (see FIG 1). Accordingly, the references taken together suggest the plurality of distal apertures as illustrated by Zawacki in order to provide varied flow ports in case one gets blocked.

With regard to claim 27, Sorenson fails to disclose that the catheter is constructed of the claimed materials. Zawacki discloses that the catheter may be made of thermoplastics such as PTFE (see column 3, lines 24-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use thermoplastics such as PTFE in the catheter disclosed by Sorenson, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

With regard to claim 28, Sorenson fails to disclose that the catheter comprises the claimed reinforcing materials. Zawacki discloses that reinforcing substances to reduce kinking may be used in the construction of the catheter, including wire (which is a metal formed as a flexible thread), which meets applicant's claim drawn to a metal (see column 4, lines 34-38). Therefore, it would have been obvious to add metal as disclosed by Zawacki to the catheter disclosed by Sorenson in order to reinforce the catheter structure, as taught by Zawacki.

With regard to claim 31, Sorenson discloses that the claimed catheter may be inserted into a patient, but does not specifically disclose the claimed method steps. Sorenson discloses that the proximal ends of the lumens are attached to a hub, which, as explained above, is capable of being removed from the lumens. Zawacki discloses providing the claimed catheter, inserting it into a venotomy site (see column 3, lines 7-22, column 9, lines 8-10), and using the catheter to remove blood, treat the removed blood, and return treated blood to the patient (see column 1, lines 15-20). With regard to

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applicant's recitation of the length of the lumens, Zawacki discloses that the inner lumen is slideable, meaning that the arterial lumen is capable of being disposed along the entire length of the venous lumen (see FIGS 2 and 3), meeting the limitations of the claim. Therefore, it would have been obvious at the time of invention to deploy the catheter disclosed by Sorenson in the manner disclosed by Zawacki, since the references, taken together, reasonably suggest the use of a coaxial dual-lumen catheter as disclosed by Sorenson in the method disclosed by Zawacki to remove, treat, and return blood to the patient.

With regard to claims 32 and 33, Sorenson and Zawacki suggest the method substantially as claimed by applicant with the exception of deploying the catheter in the claimed location and threading the catheter over a guidewire. However, Zawacki specifically discloses that the catheter may be introduced so that the catheter lies at the junction of the superior vena cava and the right atrium and that the position of the inner and outer lumens may be adjusted to provide for the correct location of the lumens within the vasculature (see column 3, lines 7-67). Therefore, it would have been obvious to place the lumens of the catheter disclosed by Zawacki in the locations claimed by applicant, since Zawacki suggests such positioning and teaches that the catheter is adjustable. With regard to the guidewire, Zawacki discloses that the catheter may be provided with a guidewire, indicating that in some applications, the catheter is deployed over a guidewire into the correct position (see column 3, lines 7-22). Therefore, it would have been obvious to deploy the catheter disclosed by Zawacki over a guidewire as

claimed by applicant, since Zawacki teaches that the catheter may be supplied with a guidewire for deployment.

With regard to claim 34 Sorenson discloses a hub, but does not specifically teach that the catheters are replaceable. Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the venous lumen or arterial lumen, depending on the operation of the catheter (see column 4, lines 5-18)—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 35 Sorenson fails to disclose the exact location of the insertion point. Zawacki discloses that the catheter may be inserted into one of the large central veins, which may include a jugular or subclavian vein (see column 2 line 65 to column 3, line 22).

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,099,58 to Sorenson et al in view of US 6,595,966 to Davey et al.

In the specification and figures, Sorenson suggests the device substantially as claimed by applicant (see rejection above) with the exception of a therapeutic agent.

With regard to claim 26, Davey discloses that a surface of the conduit may be treated with heparin, an anticoagulant, in order to prohibit deposit of materials on the surface of the conduit (see column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter suggested by the prior art with a therapeutic agent such as an

anticoagulant as disclosed by Davey in order to prevent deposit of materials on the surface of the conduit, as taught by Davey.

Response to Arguments

7. Applicant's amendment and arguments, filed 21 February 2008, with respect to the pending claims have been considered but are not persuasive.

8. Applicant argues that the Sorenson reference does not teach that the lumens are "attached to a removable" hub as claimed in the amended independent claims.

Applicant specifically argues that Sorenson teaches that the lumens are "mounted" to the hub. The Examiner respectfully disagrees with Applicant's conclusion that such mounting equates to a permanent attachment. Nowhere does Sorenson disclose that the lumens are permanently attached to the hub, and illustrates that the lumens are discrete physical entities from the hub (see the cross-hatching of elements 12, 32, and 36 in FIG 2, for example). It is the position of the examiner that the hub disclosed by Sorenson is *removable*, that is, capable of being removed from the lumens, whether by mere pulling to overcome a friction fit, or by severing the hub from the lumens. Once the hub is removed, the lumens move freely with regard to one another and are capable of being removed from one another.

9. With regard to the claimed method, Applicant claims only that the lumens *may* be removed and that the lumens *may* be separated. As such, the combined teachings of Sorenson and Zawacki suggest the method claimed by Applicant.

10. With regard to the Zawacki and Davey references, Applicant does not separately argue the applicability of each reference to the claims, instead asserting that the secondary references do not cure the deficiencies of the primary reference. The Examiner disagrees that there are deficiencies in the primary reference. The Zawacki and Davey references are held to properly recite the elements for which they have been cited.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
17 April 2008